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DATE MAILED: 10/06/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/088,047	07/11/2002	Ivar Mendez	GRON-3402	6583
5409 7	10/06/2004	EXAMINER		INER
ARLEN L. OLSEN			WILLIAMS, CATHERINE SERKE	
SCHMEISER, 3 LEAR JET L	OLSEN & WATTS		ART UNIT	PAPER NUMBER
SUITE 201		3763		
LATHAM, NY 12110		DATE MAIL ED. 10/06/200		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Comments	10/088,047	MENDEZ, IVAR				
Office Action Summary	Examiner	Art Unit				
C	Catherine S. Williams	3,763				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	6(a). In no event, however, may a reply be timwithin the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on 16 Ju	<u>ne 2004</u> .					
2a)⊠ This action is <b>FINAL</b> . 2b)□ This a	action is non-final.	•				
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-37 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1 and 8-14</u> is/are rejected.						
7)⊠ Claim(s) <u>2-7 and 15-37</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. §§ 119 and 120						
<ul> <li>12) △ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:</li> <li>1. ☐ Certified copies of the priority documents</li> <li>2. ☐ Certified copies of the priority documents</li> <li>3. ☒ Copies of the certified copies of the priority</li> </ul>	have been received. have been received in Application	on No				
application from the International Bureau * See the attached detailed Office action for a list of 13) Acknowledgment is made of a claim for domestic since a specific reference was included in the firs 37 CFR 1.78.	of the certified copies not receive priority under 35 U.S.C. § 119( $\epsilon$	e) (to a provisional application)				
a) The translation of the foreign language pro- 14) Acknowledgment is made of a claim for domestic reference was included in the first sentence of the	priority under 35 U.S.C. §§ 120	and/or 121 since a specific				
Attachment(s)						
1) Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)				

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#### **DETAILED ACTION**

### Claim Objections

The claim objections are withdrawn in light of the amendments to the claims in the Response filed 6/16/04.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Desai (US Pat# 6,461,296). Desai discloses a microinjector and a cannula with a single passageway, a blunt closed tip and a pair of side holes that are diametrically opposed and slightly offset. See figure 19A. See figures 10-13 for the embodiments of the cannula tip with side holes.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai. Desai meets the claim limitations as described above but fails to include the dimensions and materials as claimed.

At the time of the invention, it would have been obvious to make the cannula the dimensions as claimed. The Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently that the prior art device, the claimed device was not patentably distinct from the prior art device.

At the time of the invention, it would have been obvious to make the device from the materials claimed. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. The motivation for using medical grade plastics or metals would have been in order to reduce the incidence of allergic reaction of the skin to contact with non-medical grade materials.

#### Allowable Subject Matter

Claims 2-7, 15-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Response to Arguments

In response to applicant's argument that the Desai '591 reference does not teach "incremental depression of a plunger", if the prior art structure is capable of performing the

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intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, figure 25 of Desai shows a moveable elements #336 that could depress on the proximal flange of a plunger thereby being capable of effecting incremental depression of the plunger. It is noted that neither the syringe nor the syringe plunger are positive limitations of the claims and therefore, the prior art does not have to teach these elements. Additionally, this language is functional and is given limited weight in a device claim.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams (Gw). October 4, 2004

LOAN H. THANH PRIMARY EXAMINER